UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

08/07/07

DP BARCODE:	340170
MRID:	471090-01
SUBJECT:	SilvaDur™
REG. NO. OR FILE SYMBOL:	707-GRG
DOCUMENT TYPE:	Product Chemistry Review
Manufacturing-use [X] OR	End-use Product []
INGREDIENTS (PC Codes)	Silver (072501)
CAS Number:	(14701-21-4)
TEST LAB:	SafePharm Laboratories Ltd
SUBMITTER:	Rohm and Haas Company
GUIDELINE:	830 Group A & B
COMMODITIES:	Formulation
REVIEWER:	Krishna K. Deb ORGANIZATION: AD
APPROVER:	Karen P. Hicks APPROVED DATE:
COMMENT:	

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07/10/2007

TO: Marshall Swindell / Karen Leavy
PM Team 33

FROM: Krishna K. Deb, Chemist
Product Science Branch, CT Team
Antimicrobial Division (7510P)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobial Division (7510C)

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobial Division (7510C)

APPLICANT: Rohm and Haas Company
Action code: A54
Due date: 09/05/2007

Product Formulation
Active Ingredient(s)

	% by Wt
Silver…….……	….2.95
INERT INGREDIENTS ----------	-97.05
Total	100.00

BACKGROUND:

Rohm and Haas Company submitted an application for registration of a new integrated end-use product, SilvaDur™ (known also as QR-1727). This product is an antimicrobial preservative (odor control) for industrial and household to prevent the growth of bacteria, mold and mildew. The registrant provided a Confidential Statement of Formula (CSF) for the basic formulation (dated April 3, 2007).

FINDINGS:

Group A Requirements – Product Chemistry, QR-1727, Manufacturing-Use Product (MRID 471090-01)

- Group A product chemistry data requirements applicable to manufacturing-use products have been met.

Group B Requirements – Product Chemistry, QR-1727, Manufacturing-Use Product (MRID 471090-01)

- Group B product chemistry data requirements applicable to manufacturing-use products have been met, with the exception of 830.6317 (Storage Stability) and 830.6320 (Corrosion Characteristics).
- Good Laboratory Practices (GLP) statements were provided stating that the studies performed by the Rohm and Haas Company and SafePharm Laboratories Ltd. were conducted in compliance with U.S. EPA, FIFRA GLP standards and UK GLP Standards, respectively

Confidential Statement of Formula

- The requirements of PR Notice 91-2 were satisfied. The nominal concentration of the active ingredient (s) given in the revised Basic CSF agreed with the percentages declared on the product label.
- The certified limits for the active and inert ingredients given in the revised CSF were acceptable.
- All the active and inert ingredients are EPA registered for use in nonfood products.

Product Label

- The label ingredient statement, which lists the nominal concentration of the active ingredient, is consistent with information contained on the CSF.

- Certain information on the product label needs to be corrected, as follows:

- Change “CAUSES SKIN BUNS” to read “CAUSES SKIN BURNS” in the “Precautionary Statements” section of the label.

- Under the “Physical and Chemical Hazards” section of the label, add the following (or a similar) statement: “The product is not compatible with water and moderate reducing agents such as zinc.”

- Change the typeset of “STORAGE AND DISPOSAL” to be the same as the typeset of the child hazard warning.

- Change “in a sanitary landfill by incineration” to read “in a sanitary landfill, or by incineration” in the “Container Disposal” section of the label.

The label could be further improved by adding instructions to the “Pesticide Storage” section that specify what to do if the product leaks or spills from its container

RECOMMENDATIONS:

To satisfy 830.6317 (Storage Stability) and 830.6320 (Corrosion Characteristics) requirements, the applicant must provide results for a minimum of 1 year from a GLP-compliant study. Results for interim studies (i.e., 3 months) were provided. Testing of the product and packaging is continuing. Storage and disposal information on the product label needs to be revised if product composition (or packaging) deteriorates over time.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [ ]

- Are all TGAIs used registered? Yes [X] No [ ]

- Integrated formulation system [X]

- If “ME-TOO,” specify EPA Reg. No. of existing product: 707-GRG_____

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [ ] No [X]

Note: The product is not for food use.

c. Physical state of product: *Liquid*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X] No []

f. Active ingredient(s)	NC (%)	LCL (%)	UCL (%)
Silver	2.95	2.35	3.55

Note: The applicant proposed certified limits for the active ingredient that differ from the standard limits. The basis of the proposed limits appears sound and complete.

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]

- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [X] No [] Not applicable [ ]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [X] No [ ] Not applicable [ ]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes [ ] No [ ]

Note: Storage stability studies are ongoing and have not been completed.

Table A:
Product Chemistry (830 Series, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	471090-01
830.1600 Description of Materials	A	471090-01
830.1620 Production Process[2]	A	471090-01
830.1650 Formulation Process[3]	NA – The active ingredient is silver (from silver nitrate).	
830.1670 Formation of Impurities[4]	A	471090-01
830.1700 Preliminary Analysis[5]	A – The applicant provided preliminary analysis results for 5 different batches of the product.	471090-01
830.1750 Certified Limits[6]	U – The applicant proposed certified limits for the active ingredient that differ from the standard limits. The basis of the proposed limits appears sound and complete	471090-01
830.1800 Analytical Method[7]	A – A copy of a titration method was provided.	471090-01
830.1900 Submittal of Samples	[Samples are to be provided on a case-by-case basis for manufacturing-use products.]	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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[1]See Confidential Appendix A for additional information
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	At 20.0±0.5°C, the color of the product is yellow/ orange by visual assessment and 5Y 8.5/8 by the Munsell Color System.	471090-01
830.6303 Physical State	A	At 20.0±0.5°C, the product is a transparent liquid with no precipitation or sedimentation.	471090-01
830.6304 Odor	A	At 20.0±0.5°C, the product has a strong ammonium odor by nasal inhalation.	471090-01
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA	Not required for manufacturing-use products.	
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	Temperature increases were observed on the addition of water and on the addition of the reducing agent zinc powder. The results indicate that the product is not compatible with water and moderate reducing agents such as zinc phosphate or kerosene. The temperature increase observed upon the addition of 0.1M potassium permanganate was attributed to the presence of water in the potassium permanganate solution.	471090-01
830.6315 Flammability/ Flame Extension	A	The flashpoint of the product was reported to be 16±2°C (61°F; using a closed cup equilibrium method; Method A9 of Commission Directive 92/69/EEC).	471090-01
830.6316 Explodability	A	The product is not explosive at pH 11.4, 11.7, and 12.0 (using Method A14 of Commission Directive 92/69/EC).	471090-01
830.6317 Storage Stability	A	Interim storage stability study results were provided for the following conditions: storage for 3 months at 24±1°C at 50% relative	471090-01

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
		humidity in two types of containers (i.e., high molecular weight HDPE and double phenolic-lined carbon steel). The relative change of the active ingredient was +0.85% in the HDPE container, and -1.08% in the other container. The product color changed from clear yellow to hazy gold, regardless of the container type. Note: Studies using the carbon steel container have been discontinued. See 830.6320.	
830.6319 Miscibility[1]	A	The product is not an emulsifiable liquid. The product does not bear instructions for dilution with petroleum solvents.	471090-01
830.6320 Corrosion Characteristics	A	Interim corrosion characteristics study results were provided for the following conditions: storage for 3 months at 24±1°C at 50% relative humidity in two types of containers The HDPE container appears to be acceptable; studies are continuing. Changes to the carbon steel container included discoloration, peeling, and blistering of the lining after only 1 month of storage. The carbon steel container is not recommended for storage or shipping of the product.	471090-01
830.6321 Dielectric Breakdown Voltage	NA	Not required for manufacturing-use products.	
830.7000 pH[2]	A	The mean pH of the product was reported to be 9.55 at 25°C (using a procedure based on CIPAC Method MT75). A 1% aqueous dispersion of the product was used.	471090-01
830.7050 UV/Visible Absorption	NA	Not required for manufacturing-use products.	
830.7100 Viscosity	A	The mean viscocity of the product was reported to be 33.7 mm^2/s at 20.0±0.5°C; and 16.6 mm^2/s at	471090-01

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
		40.0±0.5°C (using a capillary viscometer method; specified in Method 114 of the OECD Guidelines for Testing of Chemicals).	
830.7200 Melting Point/Melting Range	NA	Not required for manufacturing-use products.	
830.7220 Boiling Point/Boiling Range	NA	Not required for manufacturing-use products.	
830.7300 Density/Relative Density/Bulk Density	A	The relative density of the product was reported to be 0.964 at 20.0±0.5°C (using the pycnometer method; Method 109 of the OECD Guidelines for Testing of Chemicals).	471090-01
830.7370 Dissociation Constants in Water	NA	Not required for manufacturing-use products.	
830.7550/830.7560/830.7570 Partition Coefficient	NA	Not required for manufacturing-use products.	
830.7840/830.7860 Water Solubility	NA	Not required for manufacturing-use products.	
830.7950 Vapor Pressure	NA	Not required for manufacturing-use products.	

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water

CONCLUSION:

This amendment , which requested approval for the registration of a new manufacturing product entitled “SilvaDur”, is accepted considering all the product chemistry data submitted under MER ID # 471090-01 and the current CSF.